NOV 2 0 2013

5. 510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

November 14, 2013

Submitter's Information [21 CFR 807.92(a)(1)]

Jan Triani
EDGE Orthopaedics
6 Mars Court, Unit 6-3
Boonton, NJ 07005
Phone: (201)543-9388
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Establishment Registration Number: TBD

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name:	EDGE Orthopaedics BITE™ Compression Screw
Common Name:	Bone Screw
Classification Name:	Class II, 21 CFR 888.3040, Product Code: HWC
Panel Code:	Orthopedics

Predicate Device [21 CFR 807.92(a)(3)]

WRIGHT™ Compression Screw (aka DART-FIRE®) – K082320 (Wright Medical Technology)
DARCO® Headless Compression Screws – K080850 (Wright Medical Technology)
DARCO® Headed Cannulated Screws – K100359 (Wright Medical Technology)

Description of the Device [21 CFR 807.92(a)(4)]

The EDGE Orthopaedics BITE™ Compression Screws include sterile titanium self- drilling and self- tapping screws. The corresponding instrumentation (depth gauges, forceps, screwdrivers, retractors, and tenaculums) to facilitate insertion is found in EDGE's RIVAL™ Instrument Tray. The cannulated compression screws are offered in a variety of diameters and lengths designed for the temporary fixation, correction or stabilization of bones. The unique low profile head design, cutting characteristics and vast screw options of the BITE Compression Screws provides extensive versatility in one comprehensive system.

Intended Use [21 CFR 807.92(a)(5)]

EDGE Orthopaedics' BITE™ Compression Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, fracture repair, and fracture fixation of bones appropriate for the size of the device. BITE Compression Screws are intended for single use only.

BITE Compression Screws are intended for use over a guide pin or wire. EDGE Orthopaedics' washers may be used with the headed screws in cases where the patient has poor bone quality.

Examples of small and long bone indications for which BITE Compression screws are used:

- Minimally invasive fracture/joint reconstructions
- Multiple-fragment joint fractures
- Simple epiphyseal fractures
  - Fractures of the head of the humerus
  - Fractures of the head of the tibia
  - Cooper fractures of the tibia
  - Fractures of the radius
- Fractures of the wrist, ankle, elbow and shoulder
- Scaphoid fractures and other fractures of the hand
- Metatarsal fractures and other fracture of the foot
- Ligament fixation of the proximal humerus
- Ligament avulsion injuries (Apohysis)
- Fractures of small joint bones
  - Malleolar fractures
  - Navicular fractures
- Fractures of the calcaneus and talus
- Arthrodesis of the ankle joint
- Avulsion fracture and metatarsal V
- Fractures of the tarsal region
- Osteotomies

BITE Compression Screws are not intended for use in the spine.

Technological Characteristics [21 CFR 807.92(a)(6)]
The subject device is similar in design, material and indications to the predicate devices.

Performance Data [21 CFR 807.92(b)(1)]
The safety and effectiveness of the EDGE Orthopaedics BITE™ Compression Screws are adequately supported by the substantial equivalence information, materials information and test results provided within this Premarket Notification.

Clinical Data [21 CFR 807.92(b)(2)]
Clinical data was not used to determine substantial equivalence.

Conclusion [21 CFR 807.92(b)(3)]
The analysis of the EDGE Orthopaedics BITE™ Compression Screws within this Premarket Notification supports the conclusion that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

ICON ORTHOPAEDIC CONCEPTS DBA EDGE ORTHOPAEDICS
Ms. Jan Triani
Director of Quality Assurance and Regulatory Affairs
6 Mars Court Unit 6-3
Boonton, New Jersey 07005

Re: K132893
Trade/Device Name: EDGE Orthopaedics BITE™ Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 7, 2013
Received: October 8, 2013

Dear Ms. Triani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K132893 page 1 of 2

Device Name: EDGE Orthopaedics BITE™ Compression Screws

Indications for Use:

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BITE Compression Screws are not intended for use in the spine.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices